



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,252	08/20/2003	Thomas Zdeblick	4002-3378/PC242.38	6078

7590 10/14/2005

Woodard, Emhardt, Moriarty, McNett & Henry LLP
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204-5137

EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
----------	--------------

3731

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.

10/644.252

Applicant(s)

ZDEBLICK ET AL.

Examiner

Julian W. Woo

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/1/05.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-50 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-25, 31-37 and 50 is/are allowed.
- 6) ☐ Claim(s) 26, 28-30 and 38-49 is/are rejected.
- 7) ☒ Claim(s) 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/1/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on July 1, 2005 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Art Unit: 3731

Claims 44 and 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Michelson (5,015,247). Michelson discloses, in the figures and in col. 8, lines 40-51 and col. 10, lines 3-14, a fusion device (50) with a solid, elongate body having a length, a pair of oppositely disposed arcuate side walls, external threads (53) extending along the length, bone growth material inducing material (bone graft) within a hollow interior of the body, at least one opening (56) extending through the one of the arcuate side walls, where the body is at least formed of a porous biocompatible material (titanium).

3. Claims 26, 28-30, 38-40, 44, and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Michelson (5,860,973). Michelson discloses, in fig. 10 and in col. 5, line 58 to col. 5, line 5 and col. 8, lines 47-61, a fusion device (400) with a solid, elongate body having a length, a pair of oppositely disposed arcuate side walls (402, 404), external threads (420) extending along the length and circumferentially interrupted by a pair of oppositely disposed truncated side walls (406), bone growth material inducing material within a hollow interior of the body, at least one opening (428) extending through the one of the arcuate side walls, where the body is at least formed of a porous biocompatible material (e.g., titanium).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3731

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (5,860,973) in view of Kaplan (5,282,861). Michelson discloses the invention substantially as claimed, but does not disclose a porous biocompatible material that is a composite comprising an open-celled substrate having interconnected porosity and infiltrated with a metal, and where the substrate is a carbonaceous material or carbon foam, where the metal is a group VB metal or tantalum. Kaplan teaches a composite comprising an open-celled substrate having interconnected porosity and infiltrated with a metal, where the substrate is a carbonaceous material or carbon foam, and where the metal is a group VB metal or tantalum. It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a composite as taught by Kaplan in the invention of Michelson. Such a material would produce a fusion device that has excellent tissue acceptance, provides a matrix for bone ingrowth, and has a formable structure that mimics bone.

Allowable Subject Matter

6. Claims 19-25, 31-37, and 50 are allowed.
7. Claim 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
8. The following is an examiner's statement of reasons for allowance: The terminal disclaimer filed on July 16, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,645,206, and the terminal disclaimer filed on November 18, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 5,669,909 have been reviewed and are accepted. The terminal disclaimers have been recorded, and they overcome the double patenting rejections in the Office actions of May 18 and October 4, 2004. Also, none of the prior art of record, alone or in combination, discloses a fusion device having, inter alia, a solid, elongate body, external threads substantially along the length of the body, and a hollow interior, where the body is formed of a porous biocompatible material, where the external threads are circumferentially interrupted by a pair of oppositely disposed truncated side walls to define a pair of arcuate side walls, where the body has opposing, tapered outer walls disposed entirely within a taper angle defined by the outer walls, where the body is substantially continuously tapered along the length, and where the body has a first diameter adjacent a first end and a larger second diameter adjacent an opposite second end.

Art Unit: 3731

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

October 6, 2005